PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

de Baetselier et al.

Serial No.: 09/596,101

Filed: June 16, 2000

For: PEPTIDES AND NUCLEIC ACIDS DERIVED FROM EISENIA FOETIDA AND THE USE THEREOF

Confirmation No.: 2709

Examiner: V. Ford

Group Art Unit: 1645

Attorney Docket No.: 2676-4432US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

August 23, 2004 Betty Vowles
Date Signature

Betty Vowles
Name (Type/Print)

DECLARATION OF ALAIN BESCHIN, Ph.D., UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, Dr. Alain Beschin, declares and states:

1. I am a named inventor or co-inventor of the invention described in one or more of the claims of U.S. Patent Application 09/596,101.

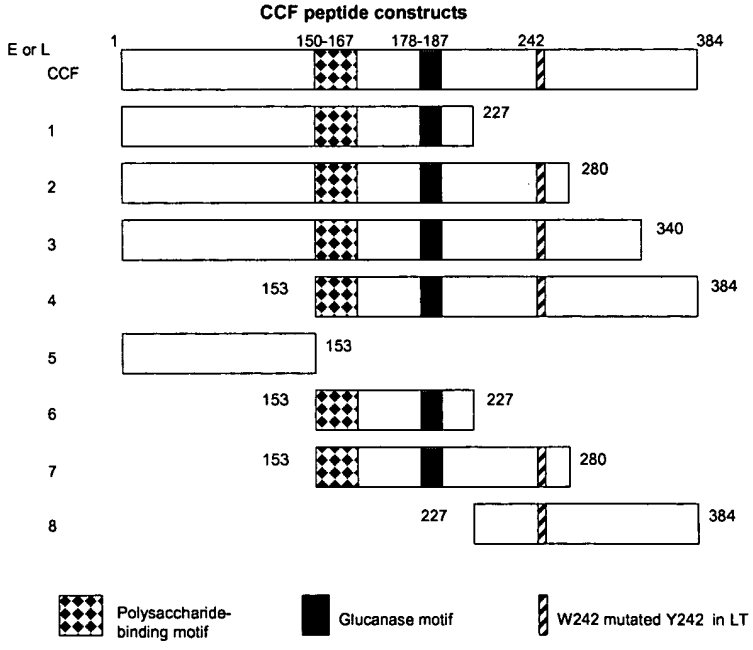
2. I am informed and believe that a communication from the United States Patent and Trademark Office was mailed on or about May 24, 2004, regarding the above-referenced application. I am informed and believe that claims 1-3, 11, 16-17 and 20 were rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement. I am also informed and believe that the communication from the United States Patent and Trademark Office asserted that there is

insufficient guidance in the specification of U.S. Patent Application 09/596,101 as to which amino acids can be deleted from a full-length CCF-1, wherein the shortened peptide would retain its trypanolytic activity.

3. I have reviewed U.S. Patent Application 09/596,101.

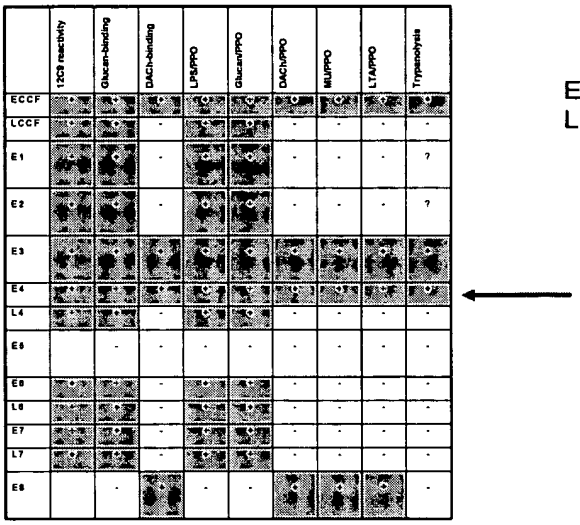
4. I performed, supervised or directed the experiments that produced the results described herein. The results indicate that one of ordinary skill in the art would be able to make and use the peptides having trypanolytic activity and the compositions including peptides having trypanolytic activity of the pending claims of U.S. Patent Application 09/596,101 without undue experimentation.

5. Peptide fragments of CCF as depicted in the following figure were constructed in accordance with the guidance disclosed at page 9 of U.S. Patent Application 09/596,101. The amino acid residues of CCF at which each of the peptide fragments start and end are indicated in the figure.



6. These peptide fragments were tested for trypanolytic activity using a trypanolytic assay such as the trypanolytic assay described at pages 14-15 of U.S. Patent Application 09/596,101. (*See also*, trypanolytic assay of International Publication WO 99/31229, pages 14-15). The results of the trypanolytic assay on the peptide fragments of the previous figure are illustrated in the following table.

Summary of the activities of CCF-derived peptides



ECCF: CCF from Eisenia
LCCF: CCF from Lumbricus

7. As illustrated in the table, peptide fragments E3 and E4 possess trypanolytic activity as determined by the trypanolytic assay.

8. As described in and in accordance with U.S. Patent Application 09/596,101, the results of the table indicate that peptide fragments of CCF (SEQ ID NO: 3) and peptides including SEQ ID NO: 1 possess trypanolytic activity as determined by the trypanolytic assay described in U.S. Patent Application 09/596,101. For instance, fragment E3 starts at amino acid 1 and ends at amino acid 340 of SEQ ID NO: 3, and fragment E4 starts at amino acid 153 and ends at amino acid 384 SEQ ID NO: 3.

9. I hereby declare that all statements are made of my own knowledge, are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful, false statements and the like so made are

punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application or any patent issued therefrom.

Dr. Alain Beschin

23/8/04
Date

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